STATE OF _____

DEPARTMENT OF _____

CHAPTER 100A-1, ADMINISTRATIVE CODE

CERTIFICATION OF ENVIRONMENTAL TESTING LABORATORIES

100A-1.001 Policy and Intent.

(1) Laboratories seeking certification to perform analyses of environmental samples shall satisfy the minimum criteria expressed in this Rule Chapter.

(2) If any section, subsection, provision, clause, or portion of this chapter is adjudged unconstitutional or invalid by a court of competent jurisdiction or in any proceeding, the remainder of this chapter shall not be affected thereby.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.003 Scope of Accreditation.

Under the NELAC Standards adopted on July 2, 1998, the tiers of laboratory testing and field sampling are defined below. The first tiers contain more general requirements for accreditation, and each successive tier contains additional requirements to demonstrate capability in more specific fields of sampling or testing. All references to the Code of Federal Regulations (CFR)

refer to the version dated _____. All CFR references and incorporated documents therein are adopted herein by reference into this Rule as well.

(1) Tier I: Legal Identity and Mission

(a) Laboratory Testing

(b) Field Sampling

(2) Tier II: Testing Capability - the general scientific discipline of testing within each business Mission identified in Tier I.

(a) Chemistry

(b) Microbiology

(c) Whole Effluent Toxicity

(d) Radiochemistry

(e) Field Measurement

(f) Microscopy

(3) Tier III: Regulatory Program - the sampling and testing protocols and Quality Assurance procedures for each Testing Capability identified in Tier II, which are required for compliance with the specified environmental monitoring regulations. The following Regulatory Programs are addressed:

(a) Clean Air Act (CAA) - Title 40 Code of Federal Regulations Parts 50 through 99 (40 CFR Parts 50 through 99).

(b) Clean Water Act (CWA) - 40 CFR Parts 100 through 140 and Parts 400 through 599.

(c) Safe Drinking Water Act (SDWA) - 40 CFR Parts 141 through 149.

(d) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) - 40 CFR Parts 150 through 189.

(e) Resource Conservation and Recovery Act (RCRA) - 40 CFR Parts 240 through 299.

(f) Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - 40 CFR Parts 300 through 399.

(g) Toxic Substances Control Act (TSCA) - 40 CFR Parts 700 through 799.

(h) STATE SUPPLEMENTAL CERTIFICATION: _____

_____

(4) Tier IV: Test Methods - the approved laboratory testing procedures within the Regulatory Programs identified in Tier III, as follows:

(a) CAA - 40 CFR Part 50 Appendices,
40 CFR Part 51 Appendix M,
40 CFR Part 52 Appendices D and E,
40 CFR Part 60 Appendices A and B,
40 CFR Part 61 Appendix B,
40 CFR Part 63 Appendices A and C,
40 CFR Part 75 Appendices D, E, and G,
40 CFR Part 79,
40 CFR Part 80 and its Appendices,
40 CFR Part 82, Subpart F,

and the documents incorporated therein by reference. Alternate test methods must be documented, evaluated, and determined to be equivalent in performance to the approved reference methods,

according to the procedures and criteria in 40 CFR Parts 53 and 63.

(b) CWA - referenced in 40 CFR Part 136,
40 CFR Part 425,
40 CFR Part 435,
40 CFR Part 455,
40 CFR Part 465,
40 CFR Part 503,
63 FR 18504, April 15, 1998,

and in the documents incorporated therein by reference. Performance-based alternate test methods may be acceptable if they are documented and evaluated to meet the same performance criteria as the referenced methods, according to the procedures and criteria in 40 CFR Part 136, Chapter 5 Appendix C of the NELAC Standards, or the documents incorporated therein by reference.

(c) SDWA - referenced in 40 CFR Part 141,
40 CFR Part 143,

and in the documents incorporated by reference therein. Alternate test methods may be used if they are documented, evaluated for satisfactory performance according to Chapter 5, Appendix C of the NELAC Standards, and listed in the Federal Register as equally effective to the approved test methods.

(d) FIFRA - referenced in 40 CFR Part 158.

(e) RCRA - referenced in 40 CFR Part 260,
40 CFR Part 261,
40 CFR Part 266,

and in the documents incorporated therein by reference. To use an alternate test method, a laboratory must petition and receive EPA approval for a regulatory amendment to add the equivalent testing method, as stipulated in 40 CFR Part 260.

(f) CERCLA - referenced in 40 CFR Part 300.

(g) TSCA - 40 CFR Part 761,
40 CFR Part 763,
40 CFR Part 795,
40 CFR Part 796,
40 CFR Part 797, and
40 CFR Part 798.

(h) STATE SUPPLEMENTAL CERTIFICATION: _____

_____

(e) Tier V: Analytes - the specific contaminants within each Test Method identified in Tier IV, which are determined in order to assess process efficacy, environmental or health impacts, regulatory compliance, or the general condition of defined systems. The analyte must be listed in the approved test method, for a testing laboratory to be certified for the analyte with that method.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.004 Categories of Certification.

(State Accrediting Authorities may need to define different combinations of Tier III, Tier IV, and Tier V Scope of Accreditation as their categories of certification, in order to apportion the available resources most effectively in meeting the workload requirements for the certification process, and to assess the appropriate certification fees equitably)_____

_____

_____

_____

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.005 Laboratory Certification Criteria.

(1) To be certified for Laboratory Testing (Tier I), a laboratory shall meet the general requirements specified in the following NELAC Standards, revised as of _____:

Section 1.8.3 - General Laboratory Requirements

Section 4.1.1 - Personnel Qualification

Section 5.0 - Introduction

Section 5.1 - Scope (of Quality System)

Section 5.4 - Organization and Management

Section 5.5 - Quality System

Section 5.6 - Personnel

Section 5.7 - Physical Facilities

Section 5.8 - Equipment and Reference Materials

Section 5.9 - Measurement Traceability and Calibration

Section 5.10 - Test Methods and Standard Operating Procedures

Section 5.11 - Sample Handling, Acceptance Policy, and Receipt

Section 5.12 - Records

Section 5.13 - Report Format and Contents

Section 5.14 - Subcontracting Samples

Section 5.15 - Outside Support Services and Supplies

Section 5.16 - Complaints

The above NELAC Standards are adopted by reference herein.

(2) To be certified for Field Sampling (Tier I), a laboratory must meet the requirements specified in Section 1.8.4 of the NELAC Standards, which is adopted herein by reference.

(3) To be certified for the Chemistry, Whole Effluent Toxicity, Microscopy, Microbiology, Radiochemistry, or Field Measurement Testing Capabilities (Tier II), a laboratory shall meet the requirements specified in the following NELAC Standards:

(a) Section 1.8.5 and Chapter 5, Appendix D.1 for Chemistry testing.

(b) Section 1.8.6 and Chapter 5, Appendix D.2 for Whole Effluent Toxicity testing.

(c) Section 1.8.7 and Chapter 5, Appendix D.3 for Microbiology testing.

(d) Section 1.8.8 and Chapter 5, Appendix D.4 for Radiochemistry testing.

(e) Section 1.8.10 for Field Measurement testing.

(f) Section 1.8.9 for Microscopy testing.

(4) To be certified under the CAA Regulatory Program (Tier III), the laboratory shall comply with the requirements specified in Chapter 5, Appendix D.5 of the NELAC Standards. A laboratory supporting specific monitoring programs must comply with the quality assurance requirements and objectives in those programs, as found in 40 CFR Part 53; 40 CFR Part 57; 40 CFR Part 58, Appendices A and B; 40 CFR Part 60, Appendix F; 40 CFR Part 61, Appendix P; 40 CFR Part 63; 40 CFR Part 75; and 40 CFR Part 79. All of the above references are adopted into this Rule herein.

(5) To be certified for Field Sampling under the CWA Regulatory Program (Tier III), the laboratory must comply with the sampling protocols specified in 40 CFR Part 122. A laboratory supporting pretreatment regulations must comply with applicable sampling protocols and analytical requirements in 40 CFR Part 403. To be certified for Laboratory Testing under this Program, the laboratory must comply with sample container, holding times, and other quality assurance requirements in 40 CFR Part 136. A laboratory testing sludges must comply with monitoring and reporting requirements in 40 CFR Part 503. All references noted above are adopted into this Rule herein.

(6) To be certified under the SDWA Regulatory Program (Tier III), a laboratory must comply with method detection limit, sample container, holding time, proficiency, and other quality assurance requirements in 40 CFR Part 141 and 40 CFR Part 143, both adopted by reference herein.

(7) To be certified under the FIFRA Regulatory Program (Tier III), the laboratory must comply with the Good Laboratory Practice standards in 40 CFR Part 160, which is adopted by reference herein.

(8) To be certified under the RCRA Regulatory Program (Tier III), a laboratory must comply with applicable groundwater quality monitoring, quality assurance, and waste testing requirements in 40 CFR Part 146, 40 CFR Part 257, 40 CFR Part 264, 40 CFR Part 265, 40 CFR Part 266, 40 CFR Part 268, 40 CFR Part 270, and 40 CFR Part 279, all adopted herein by reference.

(9) To be certified under the CERCLA Regulatory Program (Tier III), a laboratory that supports a potential Superfund site, or generates data in support of remedial investigation, feasibility studies, remedy selection, or remediation product quality, for mitigating pollutant releases from that site, shall meet the applicable requirements of 40 CFR Part 300.

(10) To be certified under the TSCA Regulatory Program (Tier III), a laboratory shall comply with the Good Laboratory Practice standards in 40 CFR Part 792. A laboratory certified for PCB’s, asbestos, and dioxins in this Program must also comply with the quality assurance requirements in 40 CFR Parts 761, 763, and 766, respectively.

(11) To be certified for specific approved Test Methods (Tier IV), the laboratory shall comply with the requirements in each approved test method, unless the corresponding NELAC Standards are more stringent, in which case the NELAC Standards shall be followed. The laboratory shall also comply with the

manufacturer’s instructions for maintaining and tuning each test equipment, optimizing test performance, and demonstrating measurement system performance, unless the corresponding test methods and NELAC Standards are more stringent, in which case the requirements of the test methods or the NELAC Standards shall be followed. All approved Test Methods and NELAC Standards are adopted herein by reference into this Rule.

(12) A laboratory using an Alternative Test Procedure or Performance-Based Measurement System in Tier IV shall supply the Accrediting Authority with a written copy of the alternate test method prior to the Accrediting Authority’s on-site inspection of the laboratory. An alternate test method can be approved only if it is equivalent to the approved Test Method in meeting defined objectives for accuracy, precision, comparability, and completeness as it relates to the determination of compliance with any regulatory concentration levels or system conditions, or if no approved Test Method is available for the requested sample analysis. Use of alternate methods may require written approval from the EPA or publication in the Federal Register.

(13) To be certified for specific Analytes (Tier V) within each approved Test Method, the laboratory shall comply with the method requirements for initial and on-going test equipment calibrations and Analyst demonstrations of precision, accuracy, and sensitivity for each analyte, unless the corresponding NELAC Standards are more stringent, in which case the NELAC Standards shall be followed. A laboratory shall comply with the provisions of Subsection (12) above for an approved test method in which the

laboratory adds analytes to the element or compound list validated in the method.

(14) The lack of requirements for analytical testing to be performed only by laboratories certified pursuant to these Rules does not diminish or negate requirements in other Rules regarding personnel, methodology, proficiency testing, quality assurance, or other requirements for data acceptability as promulgated therein.

(15) STATE SUPPLEMENTAL CRITERIA: _____
_____

Specific Authority: _____
Law Implemented: _____
History: New _____

100D-1.006 Certification Requirements.

(1) An application for certification shall be made in writing to the Department of _____, accompanied by the application fee, and shall contain at least the information listed in Sections 4.1.7 and 4.1.9 of the NELAC Standards. The NELAC Standards and Form _____, "Application for Accreditation of Environmental Testing Laboratories under NELAP," __(revision date)__ are herein adopted by reference into these rules.

(2) Separate application and certification shall be required for all laboratories maintained on separate premises

even though operated under the same management; however, separate certification is not required for separate buildings on the same or adjoining grounds or for a mobile laboratory that is performing the same accredited testing for analytes and methods as certified at the fixed laboratory and is away from the fixed laboratory for less than 90 calendar days.

(3) The laboratory shall report in writing to the Department of _____ within 30 days all changes in laboratory name, ownership, location, personnel, methodology or any other factor consistent with the information in Sections 4.1.8 and 4.3.2 of the NELAC Standards that significantly affects the performance of analyses for which the laboratory was originally certified.

(4) An application is not completed until the laboratory has fulfilled all of the following requirements:

(a) The application reviewed by the Department of _____ was found to have approved methodology as required in Rule 100A-1.003.

(b) Proficiency samples are successfully analyzed, if available in the NELAP-approved proficiency testing program, as required in Rule 100A-1.008.

(c) A written Quality Assurance Manual has been prepared as required in Rule 100A-1.009.

(d) An on-site laboratory inspection has been conducted for the test methods and analytes for which the laboratory is seeking certification, as required in Rule 100A-1.010.

(e) Certification fees are paid as required in Rule 100A-1.017.

(f) The Technical Director or Directors were found to be qualified according to Section 4.1.1 of the NELAC Standards.

(g) The laboratory responds in writing to each deficiency noted in the on-site inspection report with an acceptable plan of correction and completion date, as required in Rule 100A-1.010.

(5) Applications for certification not completed within 2 years from the date received by the Department of _____ shall expire, and certification shall be denied.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.007 Certification of Out-of-State Laboratories.

(1) The Department of _____ shall certify an out-of-state laboratory to perform environmental sample analyses provided that the laboratory complies with all the requirements in these rules.

(2) An out-of-state laboratory may be considered for reciprocal certification to perform environmental sample analyses provided:

(a) The laboratory is certified by a NELAP approved Accrediting Authority for those scientific disciplines and

regulatory programs in which the laboratory is requesting certification pursuant to this Rule.

(b) The laboratory submits to the Department of _____ an application on Form _____, copies of the laboratory's two most recent proficiency test results, and the fees required by Rule 100A-1.017.

(c) The laboratory complies with the requirements of Rule 100A-1.005, and

(d) The laboratory submits to the Department of _____ a copy of its most recent (less than 2 years old) inspection report from the Accrediting Authority, or from the Accrediting Authority’s delegated Assessor Body, together with a current copy of the laboratory's certification; a listing of the categories, analytes, and test methods certified; and the Accrediting Authority's rules and regulations regarding laboratory certification.

(3) If upon review of the documents listed in section (2) above the Department of _____ determines that the out-of-state certification program is equivalent to the requirements of this Rule, the Department of _____ will not require an on-site survey by its inspectors and certification will be granted after the assessed certification fees are paid.

(4) If upon review of the documents listed in section (2) above the Department of _____ is unable to determine that the out-of-state certification program is equivalent to the requirements of this Rule, then, in addition to

the requirements in paragraphs (2)(b) and (2)(c) above, the Department of _____ shall conduct an on-site inspection of the laboratory. The laboratory will be responsible for the cost of the on-site inspection.

(a) The Department of _____ will grant certification if the results of the inspection verify compliance with this Rule and after the invoiced certification fees are paid.

(b) If the results of the on-site survey do not indicate the laboratory's compliance with the requirements of this Rule, the laboratory's application for certification will be denied.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.008 Proficiency Testing Requirements.

(1) Applicant and certified laboratories shall participate in a proficiency testing program approved as fulfilling the requirements of Sections 2.3 and 2.6 and Chapter 2, Appendices A and B in the NELAC Standards, which is adopted by reference herein. Participation means that the laboratory will analyze and report the results of all proficiency test samples contained in the approved program for those categories and analytes with which the laboratory desires certification. Certified laboratories shall participate in proficiency testing at least twice per year for all categories and analytes certified, if available.

(2) Laboratories shall bear the cost of any subscription to a proficiency testing program required by the Department of _____ for certification purposes. The Department of _____ shall not be charged a fee for the analysis of any performance evaluation samples.

(3) All analytes within each regulatory program that are certified or pending certification must be satisfactorily analyzed, if available, on two of the most recent three proficiency testing rounds attempted. A laboratory may participate in successive testing rounds where the closing dates for reporting results are greater than 30 days but less than 7 months apart. The laboratory must authorize the approved provider, prior to the closing date, to submit the proficiency testing results to the Department of _____ concurrently with the submittal of these results to the laboratory; otherwise, the Department may refuse to consider the proficiency test results from that round for fulfilling the requirements of this Rule.

(4) Proficiency test sample results shall be considered satisfactory when they are within the acceptance limits established by the approved proficiency test sample provider, according to one of the scoring options listed in Chapter 2, Appendix C of the NELAC Standards, which is herein adopted by reference.

(5) A laboratory that meets the requirements of subsection (3) above for a particular analyte is eligible for certification for all pending test methods for that analyte. Otherwise,

certification shall be denied, suspended, or revoked for all test methods associated with that analyte.

(6) If the two failed proficiency results do not occur on consecutive testing round attempts, then certification shall be suspended and then reinstated for the same test methods suspended when the laboratory has demonstrated to the Department of _____ that it analyzed one follow-up proficiency test sample, approved beforehand by the Department of _____, for each analyte and produced results within the acceptance limits established by the approved provider.

(7) A laboratory's certification for an analyte failed on two consecutive testing round attempts shall be suspended. The laboratory must then satisfactorily analyze the analyte in the next testing round attempt, or else certification is revoked for that analyte. During the six months following the suspension, if the laboratory passes the analyte in two of the latest three testing round attempts, the Department will reinstate certification for the analyte with the same test methods that were previously suspended. Otherwise, certification for the analyte shall be revoked.

(8) An applicant or certified laboratory shall establish and maintain the accuracy and reliability of its testing procedures for analytes not available in an approved proficiency testing program through a system of internal quality management.

(9) A certified laboratory shall comply with the other requirements for enrollment, testing, proper conduct, and successful participation in the approved proficiency testing

program, as specified in Sections 2.4, 2.5, and 2.7 of the NELAC Standards, which are all adopted by reference herein.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.009 Quality Assurance Plan Requirements.

(1) The laboratory shall prepare and follow a written quality assurance plan. The plan shall be submitted to the Department of _____ for review prior to the on-site inspection of the laboratory.

(2) All Quality Assurance Plans submitted to the Department of _____ for review shall comply with the specifications in Section 5.5 of the NELAC Standards and in the regulations referenced in Rules 100A-1.005(3) through 100A-1.005(9) for Regulatory Programs, which are incorporated by reference herein. The Quality Assurance Plan must cite the laboratory's objectives for sensitivity, precision, and accuracy for each pending and certified analyte and test method.

(3) A copy of the written Quality Assurance Plan, analytical methods, quality control data, proficiency test data, and other records documenting compliance with these Rules shall be available at the laboratory for the on-site inspection.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.010 On-Site Evaluations.

(1) The Department of _____ is authorized to inspect the premises and operations of any certified laboratory or any laboratory seeking certification or change in certification under this Rule Chapter. After completion of all prerequisites specified in Rules 100A-1.006(4)(a) through 100A-1.006(4)(c), the Department of _____ shall conduct the on-site survey of the laboratory to determine compliance with all the requirements in this Rule.

(2) The Department of _____ shall inspect the premises and operations of laboratories certified or seeking certification to perform analyses pursuant to these Rules. Such inspections shall occur at least once every 2 calendar years and at such other times as the Department of _____ deems necessary to determine continued compliance with these Rules. Inspections may be unannounced and may include the on-site analysis of proficiency test samples as well as the photographing, filming, or videotaping of any portion of the laboratory, equipment, activity, samples taken, records, test results or other information related to certification under these Rules.

(3) Inspections will be unannounced only in those cases in which the Department of _____ determines this approach necessary to establish compliance. Factors such as past

record, proficiency test performance, personnel, overall laboratory performance, and complaints from the public or other regulatory agencies will be considered in making this determination.

(4) Inspections shall be conducted in accordance with Sections 3.4 - 3.7 of the NELAC Standards, which are adopted herein by reference. Inspections will include the review of quality control data. The laboratory shall analyze at least one Quality Control Sample annually for each certified analyte and methodology.

(5) Inspections of a laboratory may occur more frequently than once every two calendar years when there are complaints about the laboratory quality, questions of fraud, numerous or serious deficiencies from the previous on-site inspection, any of the changes noted in Rule 100A-1.006(3), or any other criteria in Section 3.3 of the NELAC Standards, which is adopted by reference herein.

(6) Inspections will include the on-site analysis of proficiency test samples when the Department of _____ is unable to determine compliance using more conventional methods.

(7) The laboratory shall ensure that its documented Quality System, analytical methods, quality control data, proficiency test data, laboratory standard operating procedures, and other records needed to verify compliance with Chapter 5 of the NELAC Standards, adopted by reference herein, and this Rule are available for review during the on-site laboratory inspection.

(8) The laboratory shall submit to the Department of _____ a Plan of Correction for each deficiency noted during the on-site evaluation. Form _____, "Statement of Deficiencies and Plan of Correction" is herein incorporated by reference. This submittal is due within 30 days of the laboratory receiving the inspection report, and each Plan of Correction must have an estimated completion date. If the Department determines that a Plan of Correction will not correct the deficiency cited, the laboratory will be notified in writing and will have 30 days to submit a revised Plan of Correction. If this revised Plan of Correction is unacceptable, or if the next on-site inspection of the laboratory shows that the deficiency has not been corrected, then the Department of _____ can revoke or deny certification for the affected tiers of accreditation.

Specific Authority: _____
Law Implemented: _____
History: New _____

100A-1.011 Renewal of Annual Certification.

(1) The Department of _____ will renew a laboratory's certification after receipt of a renewal invoice and renewal certification fee, provided the laboratory is maintaining compliance with this Rule, attests to such compliance, and has reported acceptable proficiency test values for the categories

and analytes certified within the 12 months prior to July 1 of each calendar year. The Renewal Attestation of Compliance, Form _____, and Environmental Testing Laboratory Renewal Invoice, Form _____, are both herein adopted by reference.

(2) A laboratory's certification shall expire on July 1 of each calender year, unless its certification has been renewed.

(3) The Department of _____ will mail the renewal invoices and attestation forms at least 30 days prior to July 1. Failure to receive a renewal invoice does not exempt laboratories from paying the renewal certification fee.

(4) A laboratory whose certification has expired may reapply for certification in accordance with Rule 100A-1.006(1).

(5) The certified laboratory shall maintain all key accreditation elements, such as facility, personnel qualifications, quality assurance plans, calibration standards, sample handling procedures, and other elements in Section 4.3.3 of the NELAC Standards, herein adopted by reference, that originally served as the basis for the laboratory's initial certification.

Specific Authority: _____
Law Implemented: _____
History: New _____

100A-1.012 Display of Certificate.

(1) A current Certificate shall be displayed at all times in a prominent place in each certified laboratory where it may be viewed by the public. The Certificate is the property of the Department of _____ and must be returned to the Department if the laboratory's entire certification is revoked, if the laboratory withdraws from the certification program, or if the Department's status as a NELAC Accrediting Authority changes. Form _____, "National Environmental Laboratory Accreditation Program" Testing Laboratory Certificate, is adopted by reference herein.

(2) The certified laboratory shall also receive an Analyte Sheet that shows all categories, analytes, and test methods for which the laboratory is certified. The Analyte Sheet will be updated each time the laboratory's scope of certification has changed. Form _____, "National Environmental Laboratory Accreditation Program" Analyte Sheet, is adopted by reference herein.

Specific Authority: _____
Law Implemented: _____
History: New _____

100A-1.013 Contractual Agreements, Records, and Reports.

(1) Laboratories performing analytical work under certification auspices shall guarantee analytical performance according to Chapter 5, Appendix D of the NELAC Standards,

adopted by reference herein, for those analytes and test methods with which they have been certified. Each certified laboratory shall maintain the documentation required in Chapter 5 of the NELAC Standards, adopted herein by reference into this Rule, for at least 5 years.

(2) SPECIFIC STATE REPORTING REQUIREMENTS:_____

_____

(3) For reporting of results, the laboratory shall comply with the laboratory report format and content requirements in Section 5.13 of the NELAC Standards, adopted on herein adopted by reference.

(4) Certified laboratories that subcontract analytical work under certification auspices to another laboratory must establish that the contracted laboratory has been certified pursuant to this Rule for the appropriate categories, test methods, and analytes. Laboratory records shall comply with Section 5.14 of the NELAC Standards and include information from the contracted laboratory that conforms to the requirements of Section 5.13 of the NELAC Standards, which is adopted by reference herein. All data reports issued by the primary laboratory that contain results reported by one or more contract laboratories shall include the certification number of each contract laboratory. The primary laboratory shall unambiguously identify in its reports which test results were produced from its laboratory analyses and the results obtained from each contract laboratory.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.014 Denial or Revocation of Certification.

(1) The Department of _____ is authorized to deny, suspend, limit, or revoke the certification of any laboratory on any of the following grounds:

(a) Making false statements on an application, sample analysis report, or on any document associated with certification in violation of Rules 100A-1.006, 100A-1.007, and 100A-1.013.

(b) Making consistent errors in field sampling or laboratory testing, or erroneous reporting, in violation of Rules 100A-1.005 and 100A-1.013.

(c) Falsifying the results of laboratory testing, or misrepresenting any information from field sampling that is critical for demonstrating regulatory compliance, in violation of Rules 100A-1.005 and 100A-1.013.

(d) Failing to employ approved sampling protocols or testing methods in the performance of laboratory activities for which certification is required, or failing to notify clients of method modifications, in violation of Rules 100A-1.003 and 100A-1.005.

(e) Failing to maintain facilities or equipment according to the laboratory's quality assurance plan, documented Quality System, approved test methods, or regulatory program mandates, in violation of Rules 100A-1.005 and 100A-1.009.

(f) Failing to report analytical test results in the required format, reporting results without using appropriate data qualifiers and without disclaiming certification auspices, or not maintaining required records of test results, in violation of Rules 100A-1.005 and 100A-1.013.

(g) Failing to participate successfully in an approved proficiency testing program when available, in violation of Rule 100A-1.008.

(h) Failing to comply with the required quality assurance program, in violation of Rules 100A-1.005 and 100A-1.009.

(i) Violating or assisting in the violation of any provision of these Rules, in violation of Rules 100A-1.001 through 100A-1.017.

(j) Falsely claiming certification credentials for those test methods and analytes with which the laboratory is not certified, in violation of Rule 100A-1.013.

(k) Failing to correct deficiencies within the time indicated in the approved plan of correction, in violation of Rule 100A-1.010(7).

(l) Failing to pay initial certification or renewal certification fees or expenses incurred by the Department of _____ as a result of inspecting an out-of-state laboratory as stipulated in Rule 100A-1.017(5) and in violation of Rule 100A-1.007(4).

(m) Failing to indicate clearly when analyses were subcontracted to a certified laboratory in violation of Rule 100A-1.013(2).

(n) Failing to respond with a plan of correction to deficiencies noted by the Department of _____ on Form _____ within 30 days, in violation of Rule 100A-1.010(8). The Statement of Deficiencies and Plan of Correction, Form _____, is herein adopted by reference.

(o) Failing to report to the Department of _____ any of the changes stipulated in Rule 100A-1.006(3).

(p) Failing to analyze Quality Control Samples for each certified analyte and methodology annually in violation of Rule 100A-1.010(4).

(q) Permitting unqualified personnel to perform analyses in violation of Rule 100A-1.005(1).

(r) Communicating and receiving communication about proficiency test sample results from any other participating laboratory or facility, prior to the closing date of the relevant study, in violation of Rule 100A-1.008(9).

(s) Receiving any portion of another participant's proficiency test sample, or sending any portion of a proficiency test sample to another laboratory or facility, prior to the closing date of the relevant proficiency study, in violation of Rule 100A-1.008(9).

(t) Failing to admit authorized Department of _____ personnel into the laboratory facility for the on-site inspection; not allowing the Department's personnel to observe the laboratory's procedures, facilities, or equipment; not allowing the Department's personnel to interview the laboratory staff; or failing to provide the information necessary to

determine compliance with all the requirements of this Rule, in violation of Rule 100A-1.010.

(u) Committing other violations specified in Sections 4.1.4(d) and 4.4 of the NELAC Standards, which are adopted by reference herein, or misrepresenting any material fact pertinent to receiving or maintaining certification.

(2) In determining the denial, revocation, suspension or limitation, the Department of _____ will consider such factors as the gravity of the offense, the danger to the public of the offense, the intent of the violation, the extent of the violation, and the proposed correction of the problem.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.015 Administrative Hearings.

(1) The Department of _____ shall take agency action in accordance with __(state regulations)___ and shall afford a person whose substantial interests are affected an opportunity for an administrative hearing in accordance with ___(state regulations)___.

(2) The Department of _____ is authorized to issue an emergency order immediately suspending the certification of a laboratory when it determines that any

condition in the certified laboratory presents a clear and present danger to public health and safety.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.016 Recertification.

Recertification after the original certification has been revoked, or reconsideration for certification after an application has been denied, shall require submission of a new application as required for initial certification in Rule 100A-1.006(1), after the designated time period specified in Section 4.4 of the NELAC Standards, which is adopted herein by reference. Reapplication shall not be required when the laboratory's certification has been suspended for a temporary period not to exceed six months and then reinstated after the deficiencies have been corrected.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.017 Fees.

(1) ___(State regulations)___ authorizes the Department of _____ to charge and collect fees for the evaluation and certification of laboratories pursuant to these rules.

(2) A nonrefundable application fee of _____ shall accompany each application. Such fee shall be assessed each subsequent application for additional analytes. The Department of _____ shall not retain this fee in circumstances where the application is not processed.

(3) In addition to the application processing fee, each laboratory shall pay to the Dapartment of _____ the following fees for the initial certification and __(time period)___ renewal for each category of certification as follows:

_____

_____

_____

_____

_____

_____

(5) The Department of _____ shall assess the expenses it incurs as a result of on-site inspection to the out-of-state laboratories, in addition to the application and certification fees in Sections 100A-1.017(2)-(3) of these rules.

(6) These fees are sufficient to meet the costs incurred by the Department of _____ in administering this certification program under the NELAC Standards adopted by reference into the rules herein.

Specific Authority: _____

Law Implemented: _____

History: New _____